

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

CHEMBIO DIAGNOSTIC SYSTEMS, INC.,

Defendant.

Case No.

**COMPLAINT FOR
PERMANENT INJUNCTION
AND OTHER EQUITABLE
RELIEF**

Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), by its undersigned attorneys, alleges as follows:

1. This is an action under Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), to secure injunctive relief against defendant for its deceptive acts and practices and false advertising in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over plaintiff's claim pursuant to 15 U.S.C. §§ 45(a), 52, and 53(b), and 28 U.S.C. §§ 1331, 1337(a) and 1345.

3. Venue in the United States District Court for the Eastern District of New York is proper under 15 U.S.C. § 53(b) and 28 U.S.C. § 1391(b).

THE PARTIES

4. **Plaintiff FTC** is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41 - 58. The FTC enforces Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, which prohibit, respectively, deceptive acts or practices, and false advertisements for food, drugs, devices, services or cosmetics, in or affecting commerce. The FTC is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate federal district court proceedings to enjoin violations of the FTC Act, and to secure such equitable relief as may be appropriate in each case.

5. **Defendant Chembio Diagnostic Systems, Inc. (“Chembio”)** is a Delaware corporation that does business at 3661 Horseblock Road, Suite A, Medford, New York 11763. Chembio advertises, markets, promotes, offers for sale, distributes or sells tests that purportedly test for infection with the human immunodeficiency virus (“HIV”) in humans (“HIV tests”). HIV is the virus that causes acquired immunodeficiency syndrome (“AIDS”), an infectious disease characterized by immune system failure. Two strains of HIV have been identified: Type 1 and Type 2. Chembio transacts or has transacted business in the Eastern District of New York.

COMMERCE

6. Defendant’s course of trade is in or affecting commerce, within the meaning of Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANT’S BUSINESS PRACTICES

7. Since at least 1996, and continuing thereafter, defendant has marketed HIV tests, including the “HIV 1 / 2 STAT-PAK Ultra Fast” test, to companies and professional users located

in the United States and abroad. In turn, these companies and professional users have distributed defendant's HIV tests to consumers, or to others who have distributed the tests to consumers.

8. For purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, defendant's HIV tests are "devices" as "device" is defined in Section 15 of the FTC Act, 15 U.S.C. §55.

9. In the course of marketing its HIV tests, defendant has represented that its tests provide accurate results. Defendant's marketing materials have contained the following statements:

- Chembio's HIV 1 / 2 STAT-PAK is a two step immunochromatographic assay which can detect the presence of HIV 1 and 2 antibodies in serum, plasma or whole blood.
- It's Simple . . . It's Accurate . . . It's Economical.
- Sensitivity of >99%. Specificity of >99.5%
- The test is designed to have comparable sensitivity to Western Blot.

DEFENDANT'S VIOLATIONS OF THE FTC ACT

10. Defendant has represented, expressly or by implication, that its HIV tests accurately detect the presence of HIV antibodies. In fact, in some instances, defendant's HIV tests have not accurately detected the presence of HIV antibodies. Therefore, defendant's representation as set forth in this paragraph is false and misleading, and constitutes a deceptive act or practice and false advertising, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

CONSUMER INJURY

11. Defendant’s violations of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, have injured and will continue to injure consumers. Absent injunctive relief by the Court, defendant is likely to continue to injure consumers and harm the public interest.

THIS COURT'S POWER TO GRANT RELIEF

12. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), authorizes this Court to issue injunctive and other equitable relief, to prevent and remedy any violations of any provision of law enforced by the FTC.

PRAYER FOR RELIEF

WHEREFORE, plaintiff FTC, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b) and this Court’s own equitable powers, requests that this Court:

- (1) enjoin defendant from violating Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, including committing such violations in connection with the offer, sale, advertising, or other promotion or distribution of HIV tests or other devices; and

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- (2) Award such additional equitable relief as the Court may determine to be just and proper.

Respectfully submitted,

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DATED: _____, 2000

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